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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,801	08/17/2000	G. John Stanton	265.0023 0101	5388

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,801

Applicant(s)

STANTON ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9,11,13-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,11,13-35 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 9 February 2004 has been received and entered in full.
2. The indicated allowability of claims **1-4, 6-9, 11, 13-26, 30-33, and 37-39** as set forth in the previous Office Action (15 December 2003) is withdrawn in view of the new grounds of rejection included herein.

Claim Objections

3. Claim **20** is objected to because of the following informalities: said claims do not have a transitional phrase (such as "comprising", "having", "consisting of"). In the interest of Examination and in view of concurrent amendment of the claims, the Examiner has read said claims to read "selected from the group consisting of". Appropriate correction is required.

Obvious-type Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-4, 6-9, 11, 13-35, and 27-39 are rejected under the judicially created doctrine of double patenting over claims 1-16 of U. S. Patent No. 6,500,798 B1 (31 December 2002) Stanton *et al.* since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

5. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows. Both the instant application and US 6,500,798 encompass a method of administering colostrinin, a constituent peptide thereof, active analogs as defined in the claims, and 34 peptides, all of which are identical. Therefore regardless of the goal of the preamble the same compounds are being administered to the same population and will have the same effects.

Therefore both the instant Application and US 6,500,798 encompass the same invention [See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993)].

Provisional Non-Statutory Double Patenting

6. Claims 1-4, 6-9, 11, 13-35, and 27-39 are rejected under the judicially created doctrine of double patenting over claims 1-17 of Application 09/641,802 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

7. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter,

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as follows. Both the instant application and Application No. 09/641,802 encompass a method of administering colostrinin, a constituent peptide thereof, active analogs as defined in the claims, and 34 peptides, all of which are identical. Therefore regardless of the goal of the preamble the same compounds are being administered to the same population and will have the same effects. Therefore both the instant Application and Application No. 09/641,801 encompass the same invention [See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993)].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 20-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Janusz *et al.*

(1987) "Immunoregulatory Properties of Synthetic Peptides, Fragments of a Proline-Rich Polypeptide (PRP) from Ovine Colostrum." Molecular Immunology 24(10): 1029-1031.

9. The claims are drawn to a method which comprises the step of contacting cells with a "immunological regulator" therein defined as colostrinin, a constituent peptide thereof, an active analog thereof wherein said analog is required to comprise a peptide having an amino acid sequence with at least 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, and a peptide selected from the group of SEQ ID NO: 1 through SEQ ID NO: 34. No other limitations are present in the claims. The preamble is not given any patentable weight as it recites a desired outcome and does impose any specific limitations on the claims *per se*, as in a select patient population or specific therapy.

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10. Janusz *et al.* teaches the administration nonapeptide (*Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro*; identical to SEQ ID NO: 31 of the instant application) to mice (pp. 1030; Figures 1 &2).

Thus Janusz *et al.* teaches the administration to mice it meets the limitations of claims 20-35.

Janusz *et al.* also meets the limitations of “a constituent peptide of colostrinin”, “an active analog thereof”, and SEQ ID NO: 31 thus meeting the limitations of claims 20-35 (pp. 1029).

11. In regards to the asserted properties of colostrinin and its peptides, it has been established that a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore if colostrinin and constituent peptides such as nonapeptide indeed have the properties as asserted by the Applicant then these limitations are met and anticipated by Janusz *et al.*

12. In view of the desired outcome of the preamble, regardless of the desired or predicted outcome, a reference which teaches the method steps anticipates the method [see *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.)]

13. Claims **20-35** are rejected under 35 U.S.C. 102(b) as being anticipated by Inglot *et al.* (1996) “Colostrinine: a Proline-Rich Polypeptide from Ovine Colostrum Is A Modest Cytokine

Inducer in Human Leukocytes.” Archivum Immunologiae et Therapiae Experimentalis 44(4): 215-224.

14. The claims are drawn to a method which comprises the step of contacting cells with a “immunological regulator” therein defined as colostrinin, a constituent peptide thereof, an active analog thereof wherein said analog is required to comprise a peptide having an amino acid sequence with at least 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, and a peptide selected from the group of SEQ ID NO: 1 through SEQ ID NO: 34. No other limitations are present in the claims. The preamble is not given any patentable weight as it recites a desired outcome and does impose any specific limitations on the claims *per se*, as in a select patient population or specific therapy.

15. Inglot *et al.* teaches the oral administration proline-rich polypeptide (PRP) also known as colostrinine or colostrinin to humans (Abstract; pp. 219; Figures 1 & 2). Thus Inglot *et al.* teaches the administration of said peptides to humans it meets the limitations of claims 20-35. Inglot *et al.* meets the limitations of “colostrinin”, “a constituent peptide of colostrinin”, and “an active analog thereof” thus meeting the limitations of claims 20-35 (pp. 1029).

16. In regards to the asserted properties of colostrinin and its peptides, it has been established that a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore if colostrinin indeed has the properties as asserted by the Applicant then these limitations are met and anticipated by Inglot *et al.*

17. In view of the desired outcome of the preamble, regardless of the desired or predicted outcome, a reference which teaches the method steps anticipates the method [see *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method

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for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.))]

Summary

18. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
April 26, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER